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In The
Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
Petitioners,

v.

OREGON, ET AL.
Respondents.

On Writ of Certiorari to the United States
Court of Appeals for the Ninth Circuit

BRIEF *AMICI CURIAE* OF CHRISTIAN MEDICAL ASSOCIATION, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS, UNION OF ORTHODOX JEWISH CONGREGATIONS OF AMERICA, NATIONAL ASSOCIATION OF EVANGELICALS AND CHRISTIAN LEGAL SOCIETY IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE* AND INTRODUCTION[1]

The **Christian Medical Association** ("CMA") was founded in 1931 and today represents over 16,000 members—primarily practicing physicians representing the entire range of medical specialties. These members share a common commitment to the principles of biblical faith and the integration of those principles with professional practice. Among other functions, the CMA Medical Ethics Commission coordinates member experts in the field of medical ethics who formulate positions on vital issues. These positions are subsequently voted upon for adoption, amendment, or rejection by over 100 elected representatives to the national convention of the Association. CMA members and their patients will be adversely affected by the use of federally controlled medications to assist suicide, a practice diametrically opposed to traditional and current medical ethical standards.

American Association of Pro Life Obstetricians and Gynecologists ("AAPLOG") is a national organization of over 2,500 obstetricians and gynecologists who reaffirm the unique value and dignity of individual human life in all stages of growth and development from conception onward.

The **Union of Orthodox Jewish Congregations of America** (the "U.O.J.C.A.") is a non-profit synagogue

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[1] *Amici Curiae* file this brief by consent of the parties, and copies of the letters of consent are on file with the Clerk of the Court. Counsel for *Amici* authored this brief in its entirety. No person or entity, other than the *Amici*, their supporters, or their counsel, has made a monetary contribution to the preparation or submission of this brief.

umbrella organization for nearly 1,000 Jewish congregations throughout the United States. It is the largest Orthodox Jewish umbrella organization in this nation. Through its Institute for Public Affairs, the U.O.J.C.A. researches and advocates the legal and public policy positions promoted by the mainstream Orthodox Jewish community. The U.O.J.C.A. has filed briefs in federal and state courts throughout the nation in cases that affect the interests of the Jewish community and American society at large.

The U.O.J.C.A. has been concerned and active with regard to the legality of physician assisted suicide. The U.O.J.C.A. filed an *amicus* brief with this Court the last time the issue was considered in *Vacco v. Quill*, 521 U.S. 793 (1997) and *Washington v. Glucksberg*, 521 U.S. 702 (1997). The U.O.J.C.A. has also worked on this matter in the federal and state legislative arenas.

The **National Association of Evangelicals** ("NAE") is a nonprofit association of evangelical Christian denominations, local churches, organizations, institutions, and individuals that includes more than 50,000 local churches from 51 denominations, as well as over 250 other religious ministries. NAE serves a constituency of over 20 million people. The Association believes that religious freedom is a gift of God and vital to the limited government which is our American constitutional republic.

The **Christian Legal Society** ("CLS"), founded in 1961, is a nonprofit interdenominational association of Christian attorneys, law students, judges, and law professors with chapters in nearly every state and most law schools. Since 1975, the Society's legal advocacy and information division, the Center for Law and Religious Freedom, has worked for the

protection of religious belief and practice, including health care providers' rights of conscience.

SUMMARY OF ARGUMENT

In *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997), the United States Supreme Court affirmed that protection of the medical profession's integrity and ethics is a legitimate state interest justifying a governmental ban on physician-assisted suicide. Agreeing with the American Medical Association ("AMA"), the Supreme Court stressed that "physician-assisted suicide is fundamentally incompatible with the physician's role as healer." 521 U.S. at 731. Given the Court's rationale in *Glucksberg*, the Attorney General has taken an eminently reasonable position that facilitating suicide by overdose is not a legitimate medical purpose for which federally controlled substances may be used. The government's position is rationally related to several important state interests, including: safeguarding the integrity and ethics of the medical profession (*id.*); protecting persons who are depressed or mentally ill from self-destructive impulses (*id.* at 730-31); and deterring physicians from practicing voluntary and involuntary euthanasia (*id.* at 732-735).

The proponents of physician-assisted suicide advance as a primary "legitimate medical purpose" for the practice that assisted suicide is necessary to treat terminally ill persons' pain. As a factual matter, this emotionally charged argument is fundamentally flawed. First, effective, non-lethal pain treatments for critically ill patients are available. According to leading medical authorities, including the AMA, terminally ill patients' pain can be controlled without resort to suicide. *See* Brief of the American Medical Association, *et al.*, as *Amici Curiae* in Support of Petitioners (herein "AMA Brief"), at 6, *Vacco v. Quill*, 521 U.S. 793 (1997); New York State Task

Force, *When Death is Sought: Assisted Suicide and Euthanasia in the Medical Context* 40 (1994). And, indeed, most persons seeking physician-assisted suicide do so for reasons other than pain control. AMA Brief, *supra*, at 6-7. Given that effective pain treatments exist, physician-assisted suicide serves no legitimate medical purpose. Second, under the Oregon Death with Dignity Act, OR. REV. STAT. §§ 127.800-127.995 (1997), physician-assisted suicide is *not* limited to persons whose pain is untreatable.

Oregon's professed interest in permitting the use of federally controlled medications to overdose critically ill patients is not a "state interest" the United States is bound to respect. First, the State has foresworn any "interest" in regulating the practice of assisting suicide by pharmaceutical means, as it does not purport to impose any standard of practice with regard to the type of medications used or the protocol for their administration. Second, Oregon can point to no accepted standard of medical practice respecting the use of federally listed barbiturates to overdose critically ill patients. Absent such a standard, the Attorney General cannot fulfill his statutory responsibility to ensure that Oregon physicians have not traversed "the accepted limits" of professional care as they prescribe listed medications for use pursuant to the Death With Dignity Act. Finally, in view of the notoriously unpredictable toxicology of barbiturates, the risk of complications in overdosing and the increased suffering of patients whose "lethal" doses turn out to be less than effective for the intended purpose, the Attorney General is not obligated to permit the use of listed barbiturates for the purpose of overdosing critically ill patients.

ARGUMENT

I. THE SUPREME COURT APPROPRIATELY RECOGNIZED IN *WASHINGTON V. GLUCKSBERG* THAT NO TRADITION OF STATE REGULATION OF PHYSICIAN ASSISTED SUICIDE EXISTS.

A. The States and the Federal Government Have Historically Protected the Medical Profession from the Practice of Physician-Assisted Suicide.

In its solid rejection of physician-assisted suicide as a fundamental right, the Supreme Court highlighted several state interests, each of which provided an independent legitimate state interest rationally related to a governmental ban on physician-assisted suicide. *Washington v. Glucksberg*, 521 U.S. 702, 728-35 (1997). The Supreme Court deemed each of these state interests "unquestionably important and legitimate" (*id.* at 735): 1) preserving human life (*id.* at 728-29); 2) preventing the serious public health problem of suicide, particularly protecting persons suffering from depression, mental illness, or untreated pain from suicide (*id.* at 729-31); 3) "protecting the integrity and ethics of the medical profession" (*id.* at 731); 4) "protecting vulnerable groups—including the poor, the elderly, and disabled persons—from abuse, neglect, and mistakes" (*id.* at 731-32); and 5) avoiding "the path to voluntary and perhaps even involuntary euthanasia" (*id.* at 732-35).

Of particular importance to *Amici*, the Supreme Court agreed with the American Medical Association ("AMA") that "physician-assisted suicide is fundamentally incompatible with the physician's role as healer." *Id.* at 731, *quoting*, AMA Code of Ethics § 2.211 (1994). In its brief to the Court in *Vacco v. Quill*, the AMA explained:

> The power to assist in intentionally taking the life of a patient is antithetical to the central mission of healing that guides both medicine and nursing. It is a power that most physicians and nurses do not want and could not control.

Brief of the American Medical Association, *et al.*, as *Amici Curiae* in Support of Petitioners (hereinafter "AMA Brief"), at 2, *Vacco v. Quill*, 521 U.S. 793 (1997). The Court affirmed that the protection of the integrity and ethics of the medical profession is a legitimate state interest justifying a governmental ban on physician-assisted suicide. *Glucksberg*, 521 U.S. at 731. *See also Sampson v. State of Alaska*, 31 P.3d 88, 97 (Alaska 2001) (ban on assisted suicide "furthers the state's protective interests by promoting the integrity of the medical profession and fostering healthy physician-patient relationships"). The Court noted that the AMA's Council on Ethical and Judicial Affairs had concluded that the "'societal risks of involving physicians in medical interventions to cause patients' deaths is too great.'" 521 U.S. at 731, *quoting* Council on Ethical and Judicial Affairs, *Decisions Near the End of Life*, 267 JAMA 2229, 2233 (1992). The AMA warned the Supreme Court that "[t]he ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics." AMA Brief, *supra*, at 5.

It would seem self-evident that the intentional infliction of death ought not to be considered an acceptable method of pain treatment, for, as this Court has observed, "In almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide." *Glucksberg*, 521 U.S. at 710. *See id.* at 723 ("[w]e are confronted with a consistent and almost universal tradition that has long rejected the asserted right, and continues explicitly to reject it today, even for terminally ill, mentally competent adults"). Laws against physician-assisted

suicide are "longstanding expressions of the States' commitment to the protection and preservation of all human life." *Id.*

Federal law reflects the national government's commitment to protecting the medical profession against physician-assisted suicide. The Assisted Suicide Funding Restriction Act of 1997, 42 U.S.C. § 14401 (1997), "prohibits the use of Federal funds to cause a patient's death, effectively prohibits the practice of assisted suicide in Federal health facilities, removes it from the scope of 'rights' under State laws of which patients must be informed under the Federal Patient Self-Determination Act, and forbids Federal subsidies to health programs or benefit packages which include assisted suicide." S. REP. NO. 106-299, "The Pain Relief Promotion Act,"at 10 (2000) (hereinafter "S. Rep. No. 106-299"). The Assisted Suicide Funding Restriction Act passed the House of Representatives, 398-16, and the Senate, 99-0. *Id.* Upon signing it, President Clinton said it "will allow the Federal Government to speak with a clear voice in opposing these practices," and "to endorse assisted suicide would set us on a disturbing and perhaps dangerous path." *Id.* at 11.

In light of this longstanding tradition of rejection of physician assisted suicide by the medical profession and both the federal government and the governments of the several States, *Amici* submit that the burden rests with Oregon to demonstrate that it has endeavored to establish assisted suicide as a medically accepted practice and has adopted professional standards to regulate the dispensing of medications for that purpose to guide the Attorney General in determining whether federally listed medications are used for "legitimate medical purposes" under the Controlled Substances Act. Oregon simply cannot meet that burden.

B. The Attorney General Properly Determined that Overdosing Critically Ill Patients Is Not a "Legitimate Medical Purpose" for the Use of Schedule II Controlled Substances.

Thrown against the self-evident proposition that medical overdosing of patients is not an appropriate form of patient care is the mistaken belief that terminally ill persons endure untreatable, unbearable pain and, therefore, should be allowed to be prescribed medications to kill themselves. But these fears are medically unsupported because effective pain treatment does exist. AMA Brief, *supra*, at 6. In fact, as the Court recognized in *Glucksberg*, "'intolerable physical symptoms are not the reason most patients request physician-assisted suicide or euthanasia.'" *Glucksberg*, 521 U.S. at 730, *quoting* Back, *et al.*, *Physician-Assisted Suicide and Euthanasia in Washington State*, 275 JAMA 919, 924 (1996). The AMA informed the Court in *Vacco* "that the demand for physician-assisted suicide does not come principally from those seeking relief from physical pain." AMA Brief, *supra*, at 6-7, *citing* Ezekiel J. Emanuel, *et al.*, *Euthanasia and Physician-Assisted Suicide: Attitudes and Experiences of Oncology Patients, Oncologists, and the Public*, 347 LANCET 1805, 1809 & nn.6, 12 (1996). Instead, according to the AMA, "[m]ost patients that request suicide do so out of concerns that, *in the future*, their pain may become intolerable, they may suffer a loss of dignity and become dependent upon others, or they will excessively burden their families." AMA Brief, *supra*, at 8, 14-15 (emphasis added). Many persons requesting physician-assisted suicide subsequently withdraw their request if their depression or fears are treated. *Glucksberg*, at 730.

Researchers Paul Bascom and Susan Tolle noted recently in an article in the Journal of the American Medical Association, "Physical pain may cause severe distress, but it *is the*

impending disintegration of the person, loss of control, and unresolved spiritual or psychological issues that may cause the most intense suffering." Bascom, P.B., and Tolle, S.W., *Responding to Requests for Physician-assisted Suicide*, 288 JAMA 91-8 (2002) (italics added). The New England Journal of Medicine, commenting on findings regarding factors reported by Oregon sufferers of Amyotrophic Lateral Sclerosis ("ALS," or "Lou Gehrig's Disease")[2] who requested assisted suicide, stated that the studies "suggest that the loss of autonomy and control" that characterize that disease were significant factors. Ganzini, L., Johnston, W.S., McFarland, B.H., Tolle, S.W. and Lee, M.A., *Attitudes of Patients With Amyotrophic Lateral Sclerosis and their Caregivers Toward Assisted Suicide*, 339 N. ENGL. J. MED. 967-973 (1998). Far stronger even than depression in predicting an interest in assisted suicide among ALS patients is hopelessness. *Id.* According to the National Institutes of Health's Ezekiel Emmanuel, "The recent focus on end-of-life care has revealed the multiplicity of interventions, besides euthanasia and [assisted suicide], that can be used to improve the quality of life of the terminally ill. Consequently, [assisted suicide] seems less necessary and desirable to ensure good end-of-life care." Emmanuel, E.J., *Euthanasia and Physician-Assisted Suicide: A Review of the Empirical Data from the United States*, 162 ARCHIVES OF INTERNAL MEDICINE 142, 144 (2002). "If society values the dying and can ensure respectful medical

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[2] ALS is a progressive, debilitating and ultimately fatal disease that attacks the motor neuron system, causing loss of function and wasting in muscle tissue. Death ordinarily ensues within three to five years after onset. Ganzini, L., Johnston, W.S., McFarland, B.H., Tolle, S.W. and Lee, M.A., *Attitudes of Patients With Amyotrophic Lateral Sclerosis and their Caregivers Toward Assisted Suicide*, 339 N. ENGL. J. MED. 967-973 (1998). ALS patients rank among the highest reported users of assisted suicide in Oregon and elsewhere.

care for all terminally ill patients, then legalized physician-assisted death should be relevant in only a small number of cases." Ganzini, L., and Block, S., *Physician Assisted Death: A Last Resort?*, 346 N. ENGL. J. MED. 1663 (2002). This view is borne out by actual experience in Oregon: of the approximately ten percent of terminal patients who seriously consider assisted suicide, only 1 in 10 specifically request it; and only 1 in 10 of those requesting it actually take a lethal prescription. Ba[illegible]n and Tolle, *supra*.

Oregon's experience under the Death With Dignity Act has confirmed the validity of the AMA's caution that pain control is not the predominant reason for seeking physician assistance in committing suicide. Only twenty-two percent of patients who requested physician-assisted suicide in the year 2004 did so in part because of "inadequate pain control" or concerns relating to it. Ore. Dept. Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005), at 15, 24 (Table 4) (hereinafter "Oregon Report 2004"). Instead, the leading "end of life concerns" reported were "losing autonomy" and "decreasing ability to participate in activities that make life enjoyable." *Id.* Moreover, despite this well-documented understanding in the medical community, Oregon has utterly failed to ensure that potentially suicidal terminal patients are being provided with necessary mental health care. In the last year, only 5% of assisted suicide patients received psychiatric evaluation, and the level has declined dramatically since the Act became operative in 1998, from 31% in that first year. *See id.*, at 13.

Further, by its explicit language, the Death With Dignity Act assumes that persons for whom pain control is feasible may nonetheless receive physician assistance in committing suicide. The Act states that "a qualified patient" may "request and obtain a prescription to end his or her life… after being fully

informed by the attending physician of… the feasible alternatives, including … pain control." ORE. REV. STATS. § 127.800(7)(e). *See also* ORE. REV. STATS § 127.815(1)(c)(E)("[t]he attending physician shall… [i]nform the patient of… [t]he feasible alternatives, including… pain control); § 127.897 (the statutory "Form of the Request" requires the patient to affirm that he or she has been "fully informed of… the feasible alternatives, including… pain control"). *See* S. REP. NO. 106-299, *supra*, at 27, *citing* Amy Sullivan, *et al., Legalized Physician-Assisted Suicide in Oregon—The Second Year*, 342 NEW ENG. J. MED. 598 (2000).

Given that most patients who seek aid in dying in Oregon and elsewhere do not do so because of complaints of ineffective pain management, and for those who do, effective pain treatments exist, and in view of the fact that spiritual and psychological factors such as the loss of enjoyment of life and loss of autonomy are the overriding reasons patients seek aid in dying, physician-assisted suicide cannot be said to serve any legitimate medical purpose. *See, e.g.*, S. REP. NO. 106-299, at 6 (bill "finds that the dispensing and distribution of controlled substances…are not legitimate medical purposes when used to assist in a suicide or euthanasia").

II. OREGON'S PROFESSED INTEREST IN PERMITTING THE USE OF FEDERALLY CONTROLLED SUBSTANCES TO OVERDOSE CRITICALLY ILL PATIENTS IS NOT A "STATE INTEREST" THE UNITED STATES IS BOUND TO RESPECT.

A proper respect for Federalism does not obligate the Attorney General to defer to State majoritarian judgments on the practice of medicine within their borders. *See generally United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001)(Attorney General was not obligated to

recognize a "medical necessity" exception to prohibition on use of cannabis pursuant to Controlled Substances Act ("CSA") despite California law authorizing medicinal use of cannabis); *United States v. Rutherford*, 442 U.S. 544, 554, n. 10 (1979)(Food and Drug Administration was not obligated to recognize express or implied exemption from requirement of demonstrating safety and efficacy of Laetrile for treatment of terminal cancer despite its legalization for such purpose by seventeen states); *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994)(Attorney General was not obligated to re-list cannabis from Schedule I to Schedule II under the Controlled Substances Act); *but cf. Raich v. Gonzales*, 352 F.3d 1222 (2003), *cert. granted*, 124 S.Ct. 2909 (2004) (holding that Commerce Clause authority does not extend to regulating intrastate noncommercial cultivation of cannabis for personal medical purposes as recommended by a patient's physician under California law). Even if deference were appropriate, the State of Oregon's professed interest in allowing its physicians to use federally controlled substances to overdose critically ill patients pursuant to the Death With Dignity Act is not a "state interest" in the regulation of medicine that the federal government is bound to respect.

A. Oregon Has Not Designated Schedule II Controlled Substances, Or Any Particular Medication, As the Appropriate Drug Regimen Under the Death With Dignity Act.

The State of Oregon asserts that its Death With Dignity Act contemplates the use of Schedule II controlled substances to allow terminally ill patients to end their own lives.[3] In fact,

[3] "The [Act] establishes tightly controlled procedures under which competent, terminally-ill adults who are under the care of an attending physician may obtain a prescription for Schedule II

neither Measure 16, the Oregon ballot initiative that inaugurated the Death With Dignity Act, nor the regulations promulgated by the Oregon Department of Health to administer the Act specifies which therapeutic protocol is to be employed by a physician. *See* ORE. STATS. § 127.800 through 127.995 (type of lethal medication unspecified); ORE. ADMIN. RULES, §§ 333-009-000 – 333-009-0030 (2004) (same). The ballot for Measure 16, which included the entire text of the proposed Act, likewise failed to specify what substances would be used for the prescription, and the measure simply referred to a prescription for "lethal drugs" without further explication. *See Kane v. Kulongoski*, 318 Ore. 593, 600, 871 P.2d 993, 997 (1994)(reviewing proposed language of Measure 16 ballot caption). Consequently, the Act cannot reasonably be viewed as an authoritative pronouncement by the citizens of Oregon on the propriety of employing Schedule II medications for the termination of life.

Moreover, Oregon's position that the Death With Dignity Act constituted "a State's decision about *specific medical uses of controlled substances* that admittedly have approved medical uses" (Brief in Opposition at 9) (emphasis added) is belied by the fact that the State does not purport to designate either the particular medication to be used for a Death With Dignity Act prescription or the proper protocol for its administration. Rather, the State has made it clear to its citizens that it affirmatively disavows any participation in that decision, instead leaving the matter to the discretion of individual physicians. *See* Oregon Department of Human Services, "FAQs About Physician-Assisted Suicide," http://egov.oregon.gov/DHS/ ph/pas/faqs.shtml (posted as of

controlled substances in sufficient kind and quantity to allow them to control the time, place and manner of their own impending death." Brief for Respondent in Opposition, at 1.

April 29, 2005).[4] To assert that Oregon has allowed by statute and regulation state-licensed physicians to assist in suicide without fearing legal consequences is not the same as demonstrating that the practice is, or even can be, conducted in accordance with generally accepted standards of practice within the profession. *See generally* Brief for the National Association of Pro-Life Nurses as *Amicus Curiae* in Support of Petitioners, filed May 9, 2005, *Gonzales v. Oregon*, No. 04-623 (explaining distinction between Oregon law and accepted medical practices). In view of the fact that Oregon's health department has washed its hands of the medically crucial decision of what substances, federally controlled or otherwise, should be used to overdose critically ill patients, it simply cannot be said that any "recommendation of the appropriate State licensing board or professional disciplinary authority" has been made under the CSA. *See* 21 U.S.C. § 823(f)(1).

B. No Accepted Standard of Medical Practice Exists Respecting the Use of Schedule II Listed Barbiturates to Overdose Critically Ill Patients.

It is undoubtedly true, as Justice O'Connor observed in *Glucksberg*, that "the ... challenging task of crafting appropriate procedures for safeguarding ... liberty interests is entrusted to the 'laboratory' of the States... in the first instance." 521 U.S. at 737 (O'Connor, J., concurring); *Oregon v. Ashcroft*, 368 F.3d 1118, at 1124 (9th Cir. 2004) (quoting

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[4] Q. What kind of prescription will a patient receive?

A. *It is up to the physician to determine the prescription.* To date, most patients have received a prescription for an oral dosage of a barbiturate.

Id. (emphasis added).

same). However, Oregon's assertion, accepted by the court of appeals, that the Attorney General's Directive contravened the principle of federalism that "state lawmakers... are the primary regulators of professional [medical] conduct," *see* 368 F.3d at 1124 (quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002), is an argument that chases its own tail. While it is a truism that "direct control of medical practice in the states is beyond the power of the federal government," 368 F.3d at 1124, quoting *Linder v. United States*, 268 U.S. 5, 18 (1925), Respondent cannot gainsay that authority over the standards for dispensing federally controlled medications has been conferred on the Attorney General by the States via Congress' enactment of the Controlled Substances Act ("CSA"). The Court in *United States v. Moore*, 423 U.S. 122 (1975), interpreted this grant of authority under the CSA to "require" the federal government "to determine the appropriate methods of professional practice." 423 U.S. at 144, quoting 42 U.S.C. § 290bb-2a.

As the Court of Appeals recognized, the CSA prohibits practitioners from prescribing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." 368 F.3d at 1122, quoting 21 C.F.R. § 1306.04. Congress granted to the Attorney General broad authority to promulgate "rules and regulations... relating to the registration and control of the... dispensing of controlled substances," 21 U.S.C. § 821, and "any rules, regulations, and procedures by which he may deem necessary and appropriate for the efficient execution of his functions." 21 U.S.C. § 871(b). To the extent a State's laws irreconcilably conflict with the CSA and its regulations, they are preempted. 21 U.S.C. § 903. The Ashcroft Directive is well within the Attorney General's authority to provide cautionary guidance to DEA-registered practitioners regarding dispensing practices that are so removed from the medical standard that they may

subject practitioners to sanctions, including potential loss of their license. *Dispensing of Controlled Substances to Assist Suicide*, 66 FED. REG. 56,607 (2001). In the case of lethal medications prescribed pursuant to the Death With Dignity Act, the Attorney General has appropriately made the determination that the use of controlled substances exceeds the bounds of accepted standards.

Of course, there is no federally-approved drug for which the primary indication is the cessation of mental or physical suffering by the termination of life. Nor could there be, since the Food and Drug Act and its implementing regulations require, among other things, that both "safety" and "efficacy" of a drug for its intended purpose (its "indication") be demonstrated in order to approve the drug for distribution and marketing to the public. *See generally Weinberger v. Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 617-21 (1973) and companion cases cited therein (discussing "safety and efficacy" regulations); *see, e.g.*, 21 C.F.R. § 314.50 (new drug application requires controlled clinical studies and showing of safety and effectiveness of product). Safety and effectiveness must be demonstrated by adequate and well-controlled studies, 21 CFR § 314.126(a), and uncontrolled or partially controlled studies are unacceptable as the sole basis to prove effectiveness. 21 C.F.R. § 314.126(e). Proof of bioequivalence (the absence of significant differences in the rate and extent to which the active ingredient becomes available when administered at the same dosages – *see* 21 C.F.R. § 320.1(e)) and bioavailability (the rate and extent to which the active ingredient is absorbed from the drug product – *see* 21 C.F.R. § 320.1(a)), are also required. *See* 21 C.F.R. § 320.21. The standards for the approval of a new indication for an existing drug (such as the barbiturates used in for assisted suicide overdoses, the primary indications of which are to produce sedation and to induce sleep), likewise mandate a

showing of proof of efficacy by two randomized and controlled trials. *See* 21 C.F.R. § 314.54 (procedure for a new indication should be supported by information as needed to support the safety and effectiveness of the drug product). The federal government regards a drugs as "misbranded" if it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

United States v. Moore, supra, held that the United States may prosecute a physician who dispenses controlled substances outside the "accepted limits" of medical practice. The defendant in *Moore* was charged with the knowing and unlawful distribution and dispensation of methadone, a Schedule II controlled substance, in violation of 21 U.S.C. § 841(a)(1). 423 U.S. at 124. The Court noted that he was shown to have been prescribing controlled substances with "little or no medical assessment or supervision" in furtherance of an alleged radical and controversial treatment for heroin addicts. *Moore*, at 127. Here, as in *Moore*, there are no guidelines or standards acceptable to the medical profession, either nationally or in Oregon, to guide the Attorney General in making determinations in individual cases regarding the safety and efficacy of using depressive narcotics to terminate life in what amounts to a highly risky and controversial State experiment in medical treatment.

It is understandable, then, that the State of Oregon does not purport to impose or even recognize any standard of practice for physicians with respect to the appropriate drug regimen for terminating critically ill patients. The Court's *Amici* believe it is legitimate under these circumstances for the Court to wonder how the State of Oregon can insist that the Federal government is bound to respect its views on what constitutes "legitimate medical practice" when Oregon itself recognizes no medical

standards for the "practice" of dispensing massive overdoses of lethal medications.

C. Medical Authority and Oregon's Actual Experience in Implementing the Death With Dignity Act Amply Demonstrate that Oregon Can Provide No Standard of Practice to Guide Physicians on Medical Assessment or Supervision in the Use of Schedule II Listed Barbiturates to Overdose Patients.

The appeals court rather disingenuously insisted that it took "no position on the merits or morality of physician assisted suicide." *Oregon v. Ashcroft*, 368 F.3d at 1123. Essentially opining on several highly disputed medical issues, the two-member panel majority effused, "[I]t is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives," *id.* at 1123, n. 5. These controversial medical issues include whether a massive overdose of barbiturates is a relatively "reliable" means of terminating life and whether death by such an overdose is "painless." Medical authority and Oregon's own ten-year experience under the Death With Dignity Act suggest the contrary.

Amici initially note that complicating Oregon's argument that only patients in "end-of-life care" are eligible to receive lethal prescriptions under the Act is the fact that it is not always medically possible to predict the course of serious diseases, as the Court recognized in *United States v. Rutherford*, 442 U.S. 544 (1979). Rejecting the notion that the "safety and efficacy" requirements of the Food, Drug and Cosmetic Act were inapplicable to the prescribing of laetrile for "terminal" cancer patients, the Court observed:

> The FDA's practice [of considering "effectiveness" of drugs used to treat terminal patients] also reflects the recognition, amply supported by expert medical testimony in this case, that with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect. Cancers vary considerably in behavior and in responsiveness to different forms of therapy. Even critically ill individuals may have unexpected remission and may respond to conventional treatment.

Id. at 556-57; *see also id.*, n. 14, quoting 42 FED.REG. 39768, 39805 (1977) (Statement of Dr. Peter Wiernik, Chief of the Clinical Oncology Branch of the National Cancer Institute's Baltimore Research Center) ("[N]o one can prospectively define the term 'terminal' with any accuracy.... Many patients who are critically ill respond to modern day management of cancer"). If no generally accepted standard exists for determining "terminal" status for purposes of eligibility for a prescription overdose under the Act, Oregon's participating physicians may operate an unaccountable regime of dispensing lethal doses to patients who might otherwise have been provided life-prolonging medical care.

Nor are standards available to guide the Attorney General in reviewing whether assisted suicide is the "best" or "most reliable" means for a physician to assist a patient in ending his or her life. Federal law mandates that the Attorney General be able to determine whether a DEA-registered physician has prescribed medications in accordance with the usual course of professional practice. *See, e.g.*, 21 U.S.C. § 802(20)(a "practitioner" is one who is "registered ... by the United States or the jurisdiction in which he practices ... to distribute [or] dispense ... .a controlled substance *in the course of professional practice*...") (emphasis added); 21 U.S.C. §

827(c)(1)(A)(record and reporting requirements of § 827 are inapplicable to narcotic drugs in Schedules II through V when prescribed "by a practitioner *in the lawful course of his professional practice*")(emphasis added); 42 U.S.C. § 1320a-7(a) and (b)(6) (authorizing the Secretary to exclude from "any Federal health care program" a physician who furnishes services "*substantially in excess of the needs of ... patients*")(emphasis added). In the case of lethal medications prescribed pursuant to the Death With Dignity Act, the Attorney General would be utterly unable to do so.

According to statistics kept pursuant to the Act by the Oregon Department of Human Services, the fast-acting barbiturate Pentobarbital is the drug of choice for assisted suicide, used in approximately two-thirds of cases. *Oregon Report 2004*, at 5; *see also* Willems, D.L., Groenewoud, J.H. and van der Wal, G., *Drugs Used in Physician-Assisted Death*, 15 DRUGS & AGING 335-40 (1999) ("Recent research, mainly from the Netherlands, has shown that high doses of barbiturates are usually effective for physician-assisted suicide."); 133 SWISS MED. WKLY. 310-317 (2003) (a barbiturate was the only drug used in 300 of 331 physician assisted suicide deaths). However, use of Pentobarbital for this purpose is problematic, since the drug is available solely in liquid injectable format. *Cf.* FDA Register of Approved Pharmaceutical Products ("Orange Book"), Appl. No. 083246 ("Nembutal"), www.accessdata.fda.gov/scripts/ cder/ob/docs/tempai.cfm (for active ingredient "pentobarbital" in "OB_Rx" database table in "Active" status showing liquid injectable form); *and id.* (search results for "pentobarbital" in same table in "Inactive" status showing numerous oral capsule and tablet forms) (posted May 5, 2005). Since most patients are unable to inject themselves, an oral solution must be formulated. There is, naturally, no pharmacokinetic data to guide the dosing for such a procedure, nor any accepted standards for concocting an oral suspension

from an injectable solution of barbiturates.

It is highly doubtful that a generally accepted protocol for lethally overdosing patients could even be developed to guide the Attorney General in determining the standard of practice for the use of controlled substances to assist suicide, given the known toxicological unpredictability of barbiturates. Barbiturates are central nervous system depressants and produce drowsiness, sedation and hypnosis. Physicians Desk Reference Electronic Library, Entry for "Nembutal" (Ovation), www.thomsonhc.com/pdrel/librarian (4/29/05). "It is difficult to predict how much of any barbiturate will be a fatal dose for any given person." Klein, A.E., *Barbiturate Poisoning*, 29 AM. JUR. PROOF OF FACTS 2d 199, § 7. While a lethal dose is generally taken to be approximately ten times the therapeutic dose, "fatal doses and various blood and tissue levels have been found to vary considerably from one individual to another." *Id.*, § 6. The requisite dosage to induce fatality depends on numerous factors, including 1) which drug or combination of drugs was ingested; 2) whether alcohol was consumed with the drug; 3) how quickly the drug is absorbed in the system; and 4) any tolerance the user may have developed. *Id.* Fatal blood drug levels vary widely for a single drug, indicating that some are able to tolerate much larger doses than others. *Id.*, § 6; *see also id.*, § 7 (discussing factors in varying degrees of tolerance among non-abusers). Moreover, a risk of vomiting accompanies barbiturate medications, rendering the lethality of the dose (and hence the "effectiveness") questionable. Oregon reported three patients who experienced vomiting complications in 2004, a complication rate of 8%. *See* Oregon Report 2004, at 24, Table 4. Reduced effectiveness or complications in taking prescribed overdoses may prolong the dying process and considerably increase patient suffering. One researcher observes:

> Terminally ill patients who are considering ingesting drugs to hasten death and persons forming opinions on such acts should understand that many factors may affect the toxicity of various drugs and chemicals used to end life and that published euthanizing recipes may be unreliable and lead to prolonged suffering.

Crouch Barbara Insley, *Toxicological Issues with Drugs Used to End Life*, in Battin, Margaret and Lippman, Arthur G., DRUGS USED IN ASSISTED SUICIDE AND EUTHANASIA 211 (Binghamton, New York 1996).

Sequelae from "ineffective" assisted suicide dosing may include gross muscle necrosis from the pooling of blood, blistering of the hands and feet, toxic psychosis, pulmonary edema with agonal respiration, and lung abscesses. Moeschlin, S., *Clinical Features of Acute Barbiturate Poisoning*, in Matthew Henry (ed.), ACUTE BARBITURATE POISONING 120-25 (Amsterdam: Excerpta Medica 1971). Because of the undesirability of these potential complications, the Dutch protocol contemplates the administration of additional drugs to ensure death when patients take voluntary doses of drugs orally:

> The use of oral agents can be effective. If oral agents are used, physicians need to be aware of the possibility that *active termination using a muscle relaxant may be necessary*.

Kimsma, Gerrit K, *Euthanasia and Euthanizing Drugs in the Netherlands*, in Battin and Lippman, *supra*, at 197-203 (emphasis added). Clearly, where neither the State or Oregon nor its medical profession can point to reliable standards to be utilized to guide physicians who seek to "effectively" overdose their patients, the Attorney General was well within his

discretion to advise that dispensing federally listed substances for the purpose is not a "legitimate medical practice."

CONCLUSION

For the reasons set forth herein, the Court's *Amici* respectfully submit that the decision of the Ninth Circuit Court of Appeals should be reversed and the case remanded to the District Court with instructions to enter judgment for the Petitioner.

Respectfully submitted,

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